Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of sweet pomegranate juice on the severity of symptoms in patients with allergic rhinitis: A double-blinded, randomized clinical trial

Protocol summary

Study aim

Determining the effect of pomegranate juice on the severity of symptoms in patients with allergic rhinitis

Design

A randomized superiority double blinded clinical trial. n=60, randomization will be conducted with blocking method through www.randomization.com

Settings and conduct

This clinical trial will be conducted in the Allergy, Ear, Nose, and Throat Clinic of Imam Reza and Qaim Hospital as a randomized, double-blind clinical trial. Patients with allergic rhinitis who visit the hospital clinic as an outpatient will be evaluated individually by a doctor. The patients who meet the conditions to enter the study are included and assigned to intervention and control groups using a simple randomization method. After obtaining the patient's consent (complete explanation of the plan), their approval is obtained. The severity of the disease in these patients will be evaluated at the beginning of the project by interviewing the doctor and using the standard Sino-Nasal Test 20 questionnaire. The result will be recorded in the questionnaire for each patient.

Participants/Inclusion and exclusion criteria

Allergic rhinitis patients People aged 18 to 60 years Exclusion criteria: Pregnancy or breastfeeding non-allergic rhinitis systemic diseases Taking herbal supplements with antioxidant properties Liver dysfunction Kidney dysfunction Thyroid disorders Epilepsy

Intervention groups

In the intervention group, patients will receive sweet pomegranate juice concentrate (ml/day 50) and antihistamine and corticosteroid drugs and in the control group, patients will receive antihistamine and corticosteroid drugs for 2 months.

Main outcome variables

Determining the severity of clinical symptoms of patients using the SNOT-20 questionnaire, Salsola-specific IgE , Th1/Th2 cytokines, interferon (IFN)-γ, and interleukin IL-4 and IL-5 concentrations before the intervention and at the end of the study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221012056153N1**
Registration date: **2023-03-16, 1401/12/25**
Registration timing: **retrospective**

Last update: **2023-03-16, 1401/12/25**
Update count: **0**

Registration date

2023-03-16, 1401/12/25

Registrant information

Name

Maryam Akaberi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of sweet pomegranate juice on the severity of symptoms in patients with allergic rhinitis: A double-blinded, randomized clinical trial

Public title
The effect of pomegranate juice on allergic rhinitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Allergic rhinitis patients Patients who have been treated with standard drugs including antihistamines and corticosteroids for at least 4 weeks and have had a poor or no response to these treatments are included in the study.
Exclusion criteria:
Pregnancy or breastfeeding Patients with non-allergic rhinitis Patients with systemic diseases Use of herbal supplements with antioxidant properties Liver dysfunction (LFT>3ULN) Kidney dysfunction (GFR<60 ml/kg/min) Thyroid disorders (based on thyroid function test) Epilepsy
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The size of each block will be 4. Then write the list of blocks and assign numbers to them, for example (AABB(1)- BBAA(2)- BABA(3)- BAAB(4)), which will be 8 blocks according to the sample size of 30 people. Then the selection of random numbers according to the site WWW.randomization.com and finally the prepared blocks will be placed in the envelope. According to the order of arrival of patients, one of the envelopes will be randomly selected and patients will be assigned to groups based on the obtained blocks.
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the non-use of placebo in the control group, only the therapists will not be informed about the assigned treatment, and the analyst will also be unaware of the assigned treatment to the two groups. Finally, after analyzing the data, the researcher who prepared the packages reveals the code A and B.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Vakilabad Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948954
Approval date
2022-05-10, 1401/02/20
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.121

Health conditions studied

1

Description of health condition studied
Allergic rhinitis
ICD-10 code
J30.4
ICD-10 code description
Allergic rhinitis, unspecified

Primary outcomes

1

Description
Determining the severity of clinical symptoms of patients (including sneezing, an itchy nose, a runny or blocked nose, itchy, red and watery eyes, a cough, the roof of mouth being itchy)
Timepoint
Beginning and end of the study (zero and 60 days)
Method of measurement
Using of Sino-Nasal Test 20 (SNOT-20)

Secondary outcomes

1

Description
The level of specific IgE
Timepoint

Beginning and end of the study (zero and 60 days)
Method of measurement
Collection of blood samples from patients

2

Description
Th1/Th2 cytokines
Timepoint
Beginning and end of the study (zero and 60 days)
Method of measurement
Collection of blood samples from patients

3

Description
Determination of interferon (IFN)-γ concentration
Timepoint
Beginning and end of the study (zero and 60 days)
Method of measurement
Collection of blood samples from patients

4

Description
Determination of interleukin IL-4 and IL-5 concentrations
Timepoint
Beginning and end of the study (zero and 60 days)
Method of measurement
Collection of blood samples from patients

Intervention groups

1

Description
Intervention group: Patients will receive sweet pomegranate juice concentrate (ml/day 50) for 2 months, in addition to taking antihistamine and corticosteroid drugs. Pomegranate concentrate refers to concentrated pomegranate juice. The concentrate is purchased from one of the concentrate production companies (Narni, Tehran, Website: https://narni.ir/). Then the concentrate is divided into syrup jars and kept in the freezer until use.
Category
Treatment - Drugs

2

Description
Control group: In the control group, patients will receive antihistamine and corticosteroid drugs for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Allergy, ear, throat and nose clinic of Imam Reza and Qaim Hospital
Full name of responsible person
Dr Mahdi Bakhshaee
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Sponsors / Funding sources

1

Sponsor
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Grant name
Mashhad University of Medical Sciences (4000758)
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity

Mashhad University of Medical Sciences
Full name of responsible person
Dr Mahdi Bakhshaee
Position
Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Part of the data, such as information related to the main outcome or similar, can be shared
When the data will become available and for how long
The access period begins 6 months after the publication of the results
To whom data/document is available
Researchers working in academic and scientific institutions or people who are also working in the industry can apply for them.
Under which criteria data/document could be used
Drug discovery
From where data/document is obtainable
Corresponding researcher
What processes are involved for a request to access data/document
one week
Comments